REMARKS/ARGUMENTS

Upon entry of this amendment, claims 1, 14-33, 35-37 and 65, 67-69, 71, 73-74, and 89-90 will be pending in this application and presented for examination. Claims 1, 37, 65, 69, 71 and 73 have been amended. Claims 3-5, 66, 70 and 72 have been canceled without prejudice or disclaimer. Claims 89 and 90 are newly added.

Independent claims 1, 65, 69, 71 and 73 have been amended to recite clindamycin phosphate as the active agent. Support is found throughout the application as originally filed and, in particular, claim 4 as filed. In addition, independent claims 1, 65, 69, 71 and 73 each recite that the composition includes a base.

Claims 89 and 90 are newly added and recite suitable bases used in the compositions. Support is found at paragraph 42, page 9. No new matter has been added with the foregoing amendments and newly added claims. Reconsideration is respectfully requested.

At the outset, Applicants and their undersigned representative wish to thank Examiners Haghighatian and Padmanabhan for the personal interview held on April 24, 2006. During this interview, a number of issues were clarified. Applicants thank Examiners Haghighatian and Padmanabhan for their time and the courtesy of extending the personal interview.

I. FORMALITIES

Claims 1, 37, 65, 69, 71 and 73 have been amended to recite that the pharmaceutically active compound is clindamycin phosphate. Applicants have surprisingly demonstrated that the addition of a base (such as potassium hydroxide), will generate the desired pH of the formulation without degradation of the active agent. Examples of suitable bases are recited in claims 89 and 90, which find support at paragraph 42, page 9.

Claims 11 and 12 have been withdrawn by the Examiner. However, the ratios recited therein are within the scope of claim 10. As such, Applicants respectfully request that these claims be rejoined.

Moreover, Applicants respectfully request that the Examiner reconsider entering method claims 75-88. These claims are commensurate in scope to the allowable product claims as method claim 75 recites the composition of claim 1. Rejoinder is respectfully requested.

II. REJECTION UNDER 35 U.S.C. § 103(a)

The Examiner has maintained the rejection of claims 1, 3-5, 10, 14-33, 35-37 and 65-74 under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent Publication No. 2003/0118511 ("Jones") in view of U.S. Patent No. 5,446,028 ("Klein"). To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Jones teaches the delivery of corticosteroid compounds that have utility in the topical treatment of skin disorders. Jones teaches the use of a buffer to stabilize the active agent, such as betamethasone valerate. Jones does not teach or suggest the use of an antibiotic agent, especially clindamycin phosphate, and its unique properties formulated into a foam.

Applicants have discovered a novel and unobvious foam formulation having clindamycin phosphate as the pharmaceutical active agent together with a base. Suitable bases are describe in the application as originally filed at paragraph 42, page 9. These bases include, for example, bicarbonates, carbonates, and hydroxides such as alkali or alkaline earth metal hydroxides as well as transition metal hydroxides. Preferably, the base is potassium hydroxide. As shown in Figure 3, clindamycin phosphate in a traditional buffer system is degraded. However, with the addition of a base, the composition is unexpectedly stable and efficacious.

The present invention is drawn to clindamycin phosphate, which is formulated into a quick-breaking foam vehicle. The clindamycin phosphate is a prodrug ester and is stable to any significant hydrolysis within the pressurized container. Thus, no significant amount of "phosphoric acid" is being formed *in situ* within the container. After release from the container to form a quick-breaking temperature sensitive foam, and upon application to the skin, the prodrug is hydrolyzed to the clindamycin active agent. Such an antibiotic formulation is not taught or even suggested in Jones.

The secondary reference of Klein does not supply the deficiencies of the primary reference. Klein teaches a composition of benzoyl peroxide and an antibiotic in the form of an aqueous gel. Klein further teaches liquid suspensions and emulsions as well as creams, ointments and powders. (See, column 3, lines 38-42.) However, Klein does not teach or suggest foams or mousses as presently taught and claimed.

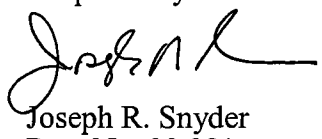
In view of the foregoing, a skilled person would have no motivation to modify the prior art references to prepare the composition as presently claimed. As such, Applicants respectfully request that the Examiner withdraw the rejection and send this application to issue.

III. CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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